K082115

11. Summary of Safety and Effectiveness

JAN 15 2009

Submitter

Name of company: S&C Polymer Silicon- und Composite Spezialitaeten GmbH
Address: Robert-Bosch-Strasse 5, D-25335 Elmshorn (Germany)
Phone: 0049 4121 483 0
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Contact Person: Dr. Christian Boettcher

Date of preparation: July 2008

Device Name:

Trade name: PhoGlass
Common Name: PhoGlass (consisting of Fill, Core, Seal, Prime and Protect)
Classification Name: Cement Dental, per 21CFR § 872.3275

Devices for which Substantial Equivalence is Claimed:

PhoGlass Fill: Fuji IX GP Extra / PhoGlass Core: Fuji IX GP Extra
PhoGlass Seal: Fuji VII / PhoGlass Prime: GC Dentin Conditioner
PhoGlass Protect: GC Fuji Varnish

Device description:

PhoGlass is a system consisting of a Glass Ionomer restorative dental material suitable for restorative-, core build-up-, and sealing-purposes. In addition it contains a dentine/ enamel conditioner and a liquid suitable for protective coatings of the restorations

Intended Use of the Device:

System for the restoration of cavities, also suitable for , core-build-up- and sealing applications. Conditioning of dentin and enamel and protecting of restored areas.

Substantial Equivalence:

PhoGlass is substantially equivalent to other legally marketed devices in the United States. The products marketed by S&C Polymer Silicon- und Compositen Spezialitaeten GmbH function in a manner similar to and is intended for the same use as the products marketed by GC.

PhoGlass Prime:

PhoGlass Prime is intended to be used as a conditioner for dentin and enamel to enhance the bond between the cements and the tooth structure.

PhoGlass Protect:

PhoGlass Protect is intended for protecting PhoGlass restorations from exposure to moisture.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: Yes or Over-The-Counter Use: No

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr Christian Boettcher
Official Correspondent
S & C Polymer GmbH
Robert-Bosch- Strasse 5
D-25335 Elmshorn, Germany

JAN 15 2009

Re: K082115
Trade/Device Name: PhoGlass Fill, Core, Seal, Prime and PhoGlass Protect
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF, EBL, LBH
Dated: December 17, 2008
Received: December 18, 2008

Dear Dr Boettcher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

9. **Statement of Indication for Use**

510(k) Number (if known): K 082115

Device Name: PhoGlass

Indications for Use:

PhoGlass Fill:

PhoGlass Fill is intended to be used as an insoluble filling cement for uniplanar fillings of class I, III and V cavities, for primary tooth fillings, for linings of composite fillings and also for core build-ups.

PhoGlass Core:

PhoGlass Core is intended to be used as an insoluble core build-up cement and for underlinings of composite fillings.

PhoGlass Seal:

PhoGlass Seal is intended to be used as an insoluble sealing cement for hypersensitivity prevention and control, for root surface protection, for fissure protection and for intermediate restorations of lesions.

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K082115